

## KEYTRUDA® (pembrolizumab) + lenvatinib in the treatment of adults with advanced/recurrent endometrial cancer that has progressed on or following prior treatment with platinum-containing therapy in any setting, and who are not candidates for curative surgery or radiation

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Please refer to the full Summary of Product Characteristics for KEYTRUDA, and patient-targeted Risk Minimisation Materials, before prescribing KEYTRUDA.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme (UK) Limited (Tel: 020 8 154 8000). By clicking the above link, you will be taken to the MHRA website.

**FOR UK HEALTHCARE PROFESSIONALS ONLY**



[Please click here for the UK KEYTRUDA Prescribing Information.](#)

[Please click here for the UK lenvatinib Prescribing Information.](#)

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# Slide deck navigation



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# KEYNOTE-775: Overview



Click the links below to navigate to the section of interest

**Study design**

**Baseline  
characteristics in  
the ITT population**

ITT, intention-to-treat.

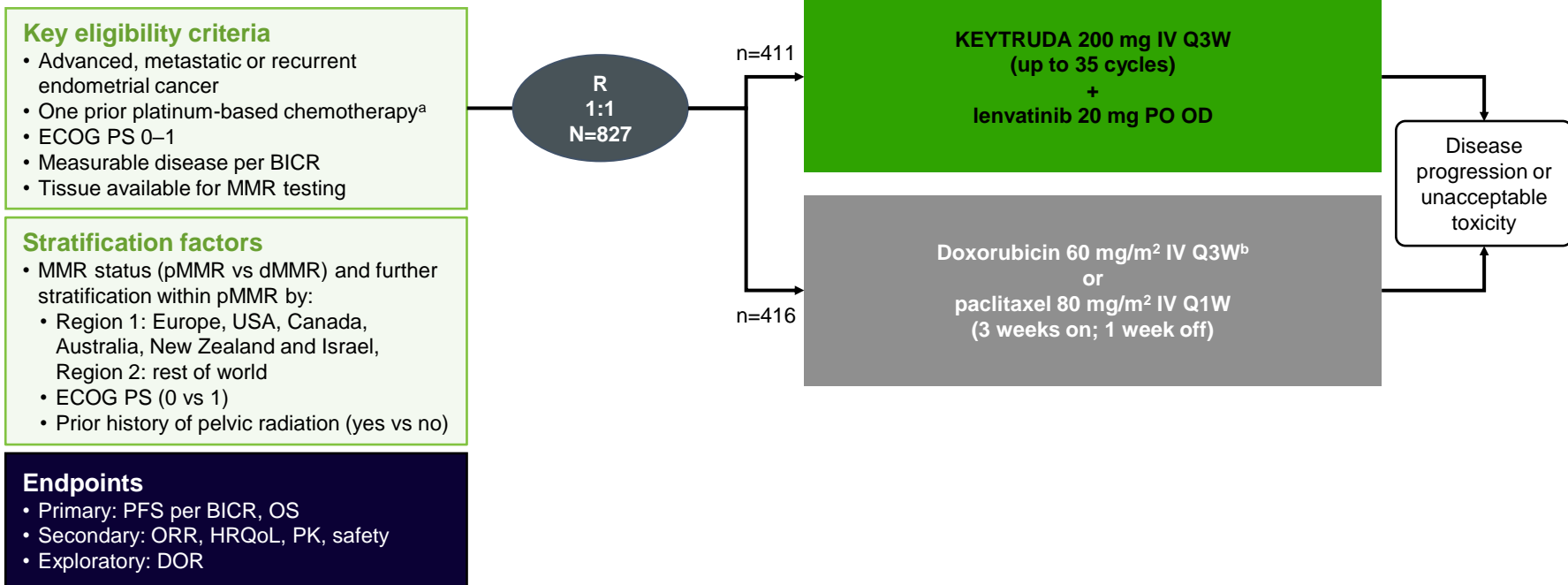
Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: Study design

Randomised, open-label, Phase 3 study



<sup>a</sup>Patients could receive up to two prior platinum-based chemotherapy regimens if one was given in the neoadjuvant or adjuvant setting; <sup>b</sup>Maximum cumulative dose of 500 mg/m<sup>2</sup>.

BICR, blinded independent central review; dMMR, mismatch repair deficient; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; IV, intravenous; MMR, mismatch repair; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; pMMR, mismatch repair proficient; PO, orally; Q1W, every week; Q3W, every 3 weeks; OD, once daily; R, randomisation.

Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: Baseline characteristics in the ITT population

Characteristic, n (%) <sup>a</sup>	KEYTRUDA + lenvatinib (n=411)	Chemotherapy (n=416)
Age		
Median (range), years	64 (30–82)	65 (35–86)
<65 years	206 (50.1)	204 (49.0)
Race <sup>b</sup>		
White	261 (63.5)	246 (59.1)
Black	17 (4.1)	14 (3.4)
Asian	85 (20.7)	92 (22.1)
Geographic region		
Region 1 <sup>c</sup>	234 (56.9)	240 (57.7)
Region 2 <sup>d</sup>	177 (43.1)	176 (42.3)
MMR status		
pMMR	346 (84.2)	351 (84.4)
dMMR	65 (15.8)	65 (15.6)

Characteristic, n (%)	KEYTRUDA + lenvatinib (n=411)	Chemotherapy (n=416)
ECOG PS		
0	246 (59.9)	241 (57.9)
1	164 (39.9)	175 (42.1)
History of pelvic radiation	174 (42.3)	186 (44.7)
Histological features at initial diagnosis		
Endometrioid carcinoma	243 (59.1)	254 (61.1)
High grade	94 (22.9)	90 (21.6)
Low grade	59 (14.4)	54 (13.0)
Not specified <sup>e</sup>	90 (21.9)	110 (26.4)
Serous carcinoma	103 (25.1)	115 (27.6)
Clear cell carcinoma	30 (7.3)	17 (4.1)
Mixed features	22 (5.4)	16 (3.8)

<sup>a</sup>Unless stated otherwise; <sup>b</sup>Race was reported by the patient. Data on race were missing for 36 patients (8.8%) in the KEYTRUDA + lenvatinib group and 44 (10.6%) in the chemotherapy group. Other races or ethnic groups (reported by 12 patients [2.9%] in the KEYTRUDA + lenvatinib group and by 20 [4.8%] in the chemotherapy group) included American Indian or Alaska Native, Native Hawaiian or other Pacific Islander and multiple; <sup>c</sup>Europe, USA, Canada, Australia, New Zealand and Israel; <sup>d</sup>Rest of world; <sup>e</sup>Included endometrioid carcinoma (grade not specified) and endometrioid carcinoma with squamous differentiation. Table adapted from Makker V et al. *N Engl J Med* 2022. dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)



# KEYNOTE-775: Results (interim analysis)



Click the links below to navigate to the section of interest

**KEYTRUDA + lenvatinib  
demonstrated superior  
PFS vs chemotherapy  
in all patients**

**KEYTRUDA + lenvatinib  
demonstrated superior  
PFS vs chemotherapy  
in patients who were  
pMMR**

**KEYTRUDA + lenvatinib  
demonstrated superior  
OS vs chemotherapy in  
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**KEYTRUDA + lenvatinib  
demonstrated superior  
OS vs chemotherapy in  
patients who were  
pMMR**

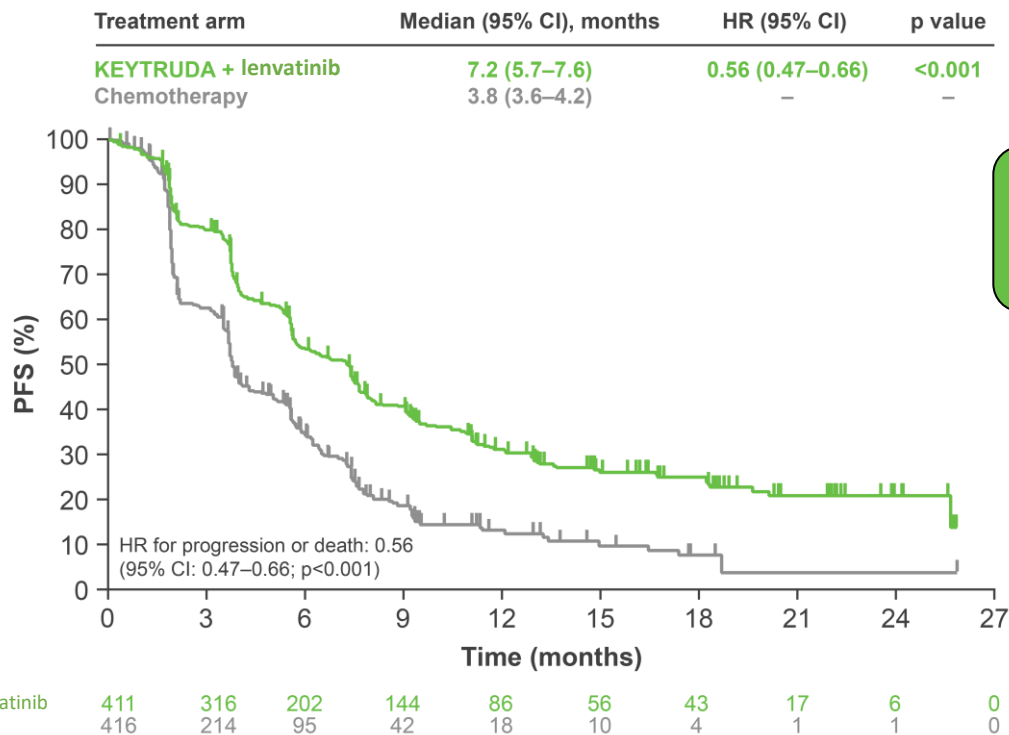
OS, overall survival; PFS, progression-free survival;  
pMMR, mismatch repair proficient.

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: KEYTRUDA + lenvatinib demonstrated superior PFS vs chemotherapy in all patients (interim analysis)<sup>a,1,2</sup>



A **44% reduction in the risk of progression or death** was observed with KEYTRUDA + lenvatinib vs chemotherapy in the ITT population (HR 0.56, 95% CI: 0.47–0.66; p<0.001)

The forest plot for PFS in patients who were pMMR and in key subgroups is shown in the appendix. [Click here](#) to view.

Analysis cut-off date: 26 October 2020.

<sup>a</sup>By BICR per RECIST v1.1. Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

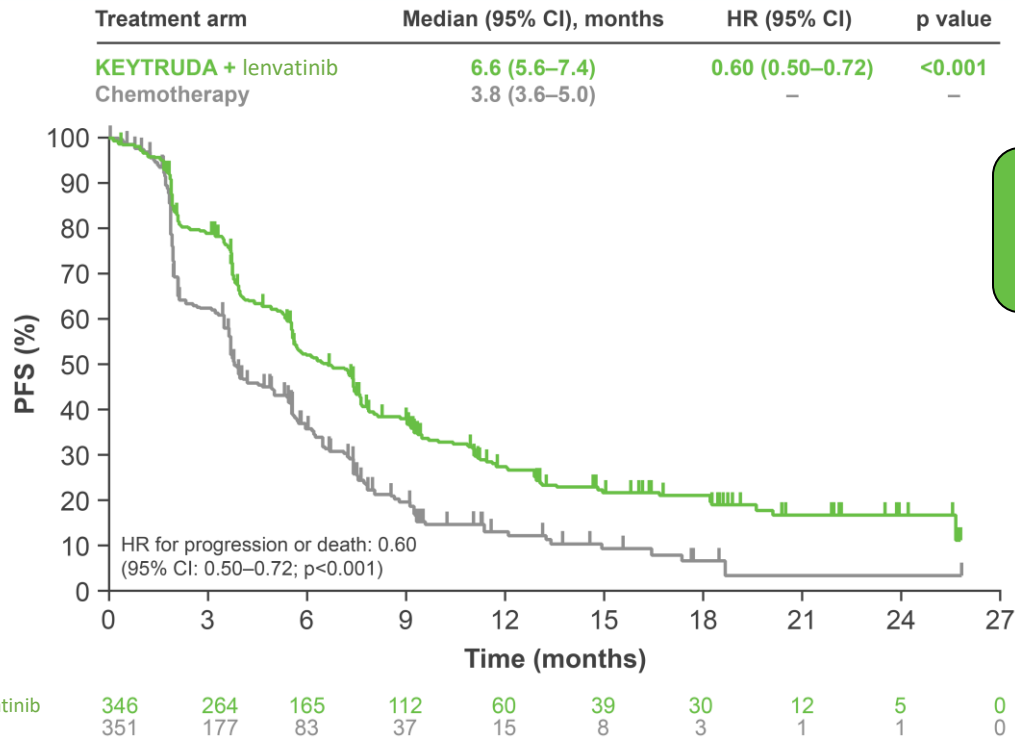
BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; PFS, progression-free survival; pMMR, mismatch repair proficient; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: <https://www.medicines.org.uk/emc/product/2498/smpc>. Accessed June 2025.





# KEYNOTE-775: KEYTRUDA + lenvatinib demonstrated superior PFS vs chemotherapy in patients who were pMMR (interim analysis)<sup>a,1,2</sup>



**A 40% reduction in the risk of progression or death** was observed with KEYTRUDA + lenvatinib vs chemotherapy in the pMMR population (HR 0.60, 95% CI: 0.50–0.72; p<0.001)

Analysis cut-off date: 26 October 2020.

<sup>a</sup>By BICR per RECIST v1.1. Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; PFS, progression-free survival; pMMR, mismatch repair proficient; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1.

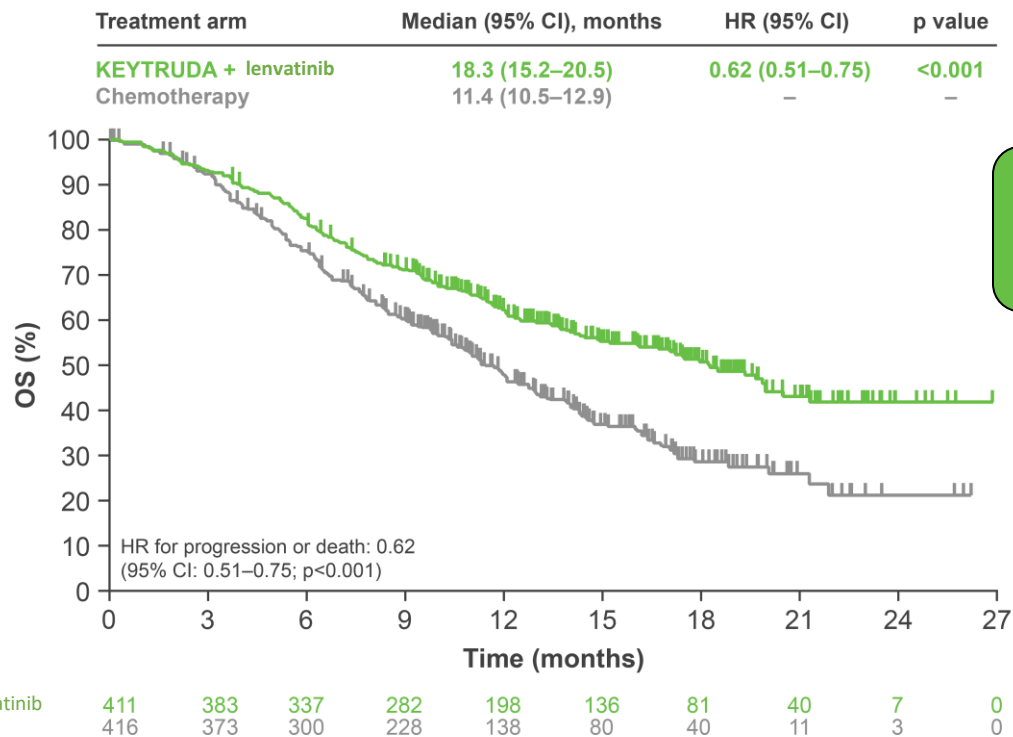
1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: <https://www.medicines.org.uk/emc/product/2498/smpc>. Accessed June 2025.







# KEYNOTE-775: KEYTRUDA + lenvatinib demonstrated superior OS vs chemotherapy in all patients (interim analysis)<sup>1,2</sup>



A **38% reduction in the risk of death** was observed with KEYTRUDA + lenvatinib vs chemotherapy in the ITT population (HR 0.62, 95% CI: 0.51–0.75; p<0.001)

The forest plot for OS in patients who were pMMR and in key subgroups is shown in the appendix. [Click here](#) to view.

Analysis cut-off date: 26 October 2020.

Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

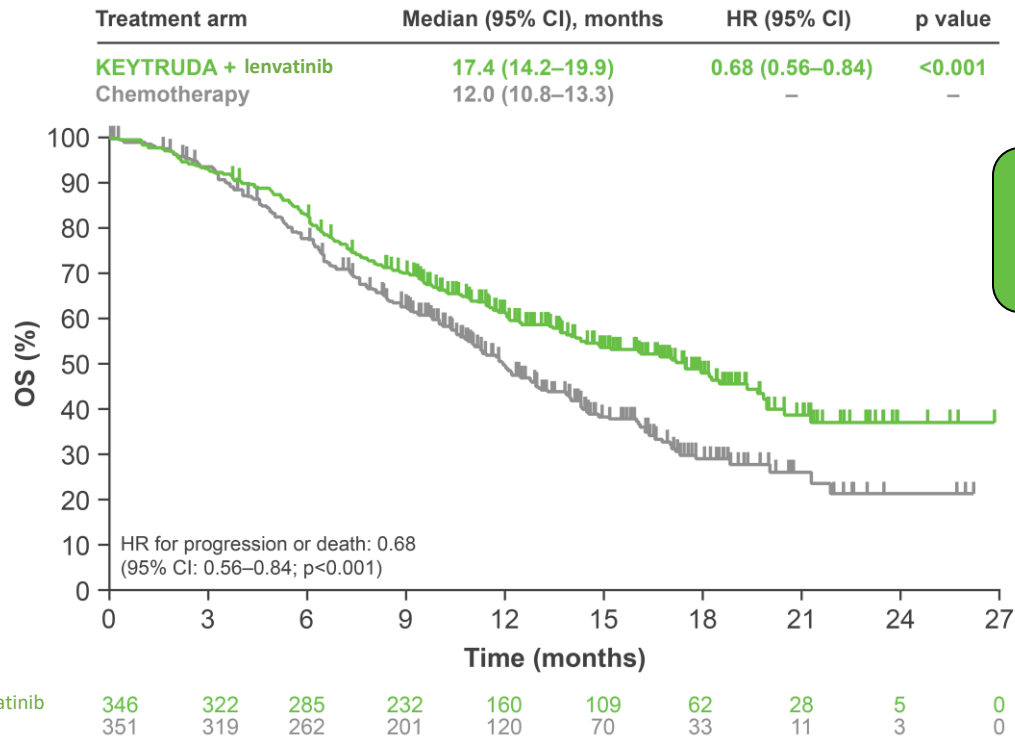
CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: <https://www.medicines.org.uk/emc/product/2498/smpc>. Accessed June 2025.





# KEYNOTE-775: KEYTRUDA + lenvatinib demonstrated superior OS vs chemotherapy in patients who were pMMR (interim analysis)<sup>1,2</sup>



A 32% reduction in the risk of death was observed with KEYTRUDA + lenvatinib vs chemotherapy in the pMMR population (HR 0.68, 95% CI: 0.56–0.84; p<0.001)

Analysis cut-off date: 26 October 2020.

Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: <https://www.medicines.org.uk/emc/product/2498/smpc>. Accessed June 2025.



# KEYNOTE-775: Results (final analysis)



Click the links below to navigate to the section of interest

**KEYTRUDA + lenvatinib  
presented superior PFS  
vs chemotherapy in all  
patients**

**KEYTRUDA + lenvatinib  
presented superior PFS  
vs chemotherapy in  
patients who  
were pMMR**

**KEYTRUDA + lenvatinib  
presented superior OS  
vs chemotherapy in all  
patients**

**KEYTRUDA + lenvatinib  
presented superior OS  
vs chemotherapy in  
patients who  
were pMMR**

**KEYTRUDA + lenvatinib  
presented superior  
ORR and DOR vs  
chemotherapy in  
all patients**

**KEYTRUDA + lenvatinib  
presented superior ORR  
and DOR vs  
chemotherapy in patients  
who were pMMR**

**Summary of AEs in all  
treated patients**

**AEs with  $\geq 25\%$   
incidence in either arm**

**TEAEs with  $\geq 10\%$   
incidence in either arm**

AE, adverse event; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient; TEAE, treatment-emergent adverse event.

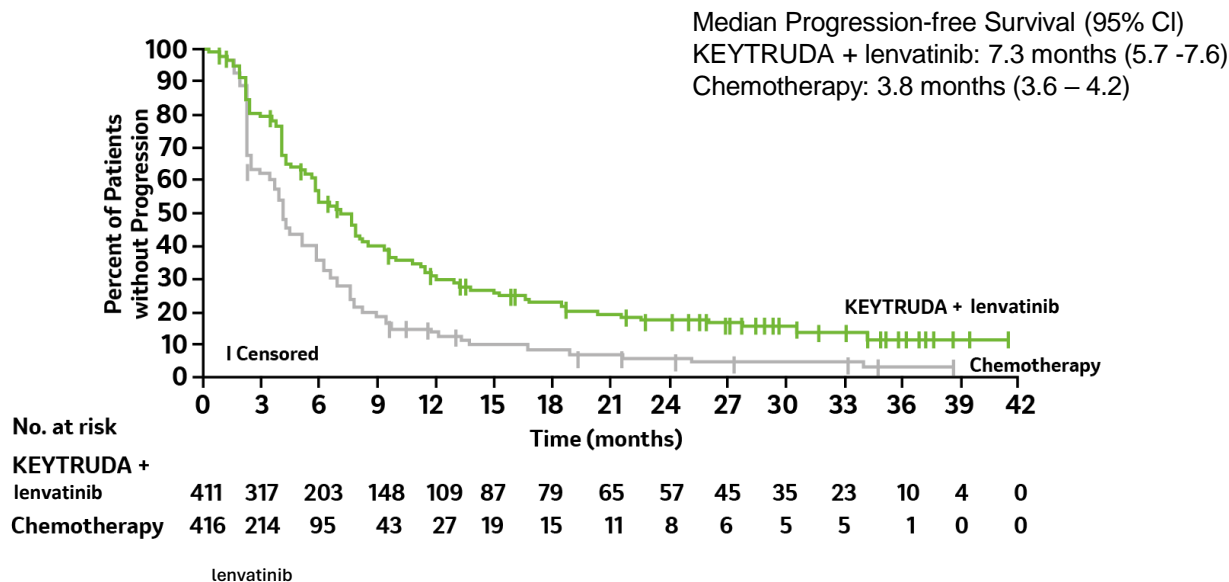
Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior PFS vs chemotherapy in all patients at the final analysis (nominal p-value)<sup>a,1,2</sup>

## All-Comer Population



A **44% reduction in the risk of progression or death** was presented with KEYTRUDA + lenvatinib vs chemotherapy in the ITT population (HR 0.56, 95% CI: 0.48–0.66; **nominal p-value<0.0001**)

Analysis cut-off date: 1 March 2022.

<sup>a</sup>By BICR per RECIST v1.1. Figure adapted from Makker V et al. *Presented at ESMO 2022*. Tick marks indicate censored data.

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; PFS, progression-free survival; pMMR, mismatch repair proficient; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1.

1. Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022; 2. MSD data on file.

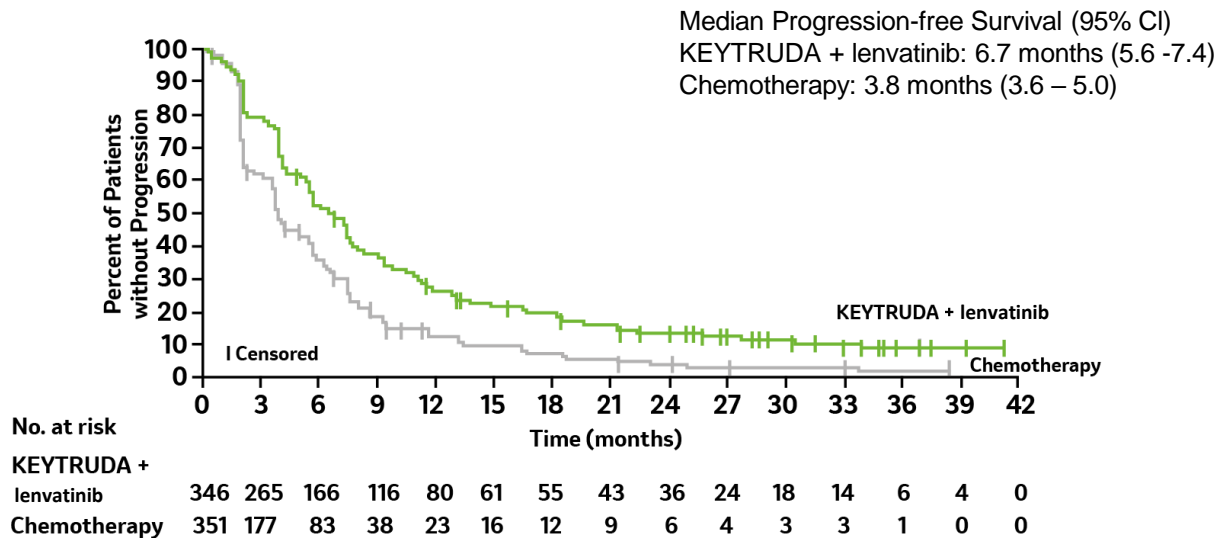
Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior PFS vs chemotherapy in patients who were pMMR at the final analysis (nominal p-value)<sup>a,1,2</sup>

## pMMR Population



**A 40% reduction in the risk of progression or death** was presented with KEYTRUDA + lenvatinib vs chemotherapy in the pMMR population (HR 0.60, 95% CI: 0.50–0.72; **nominal p-value<0.0001**)

Analysis cut-off date: 1 March 2022.

<sup>a</sup>By BICR per RECIST v1.1. Figure adapted from Makker V et al. *Presented at ESMO 2022*. Tick marks indicate censored data.

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; PFS, progression-free survival; pMMR, mismatch repair proficient; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1.

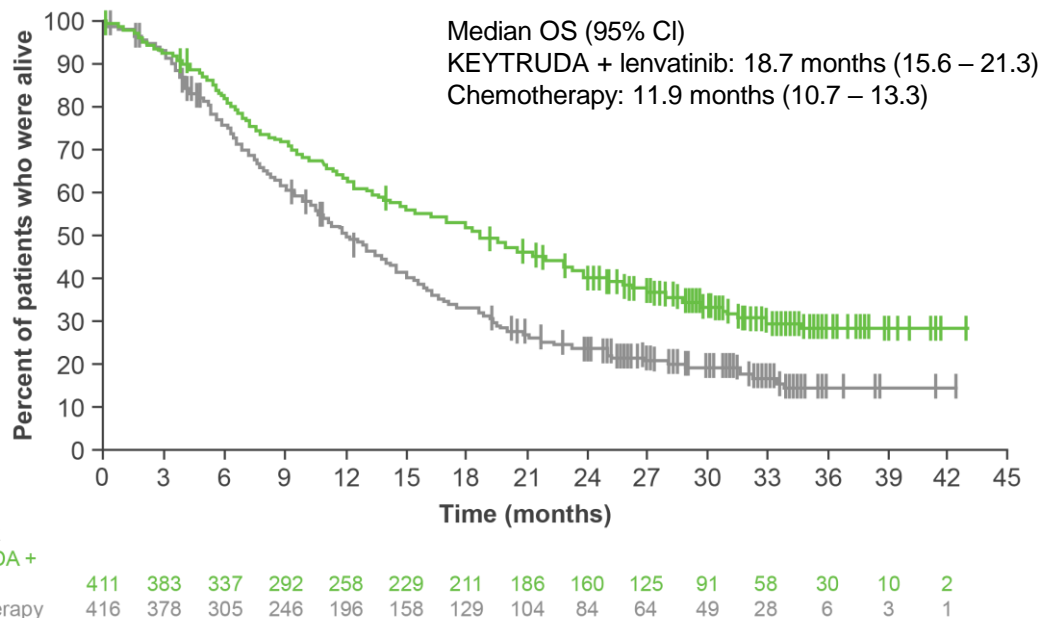
1. Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022; 2. MSD data on file.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior OS vs chemotherapy in all patients at the final analysis (nominal p-value)<sup>1-3</sup>



**A 35% reduction in the risk of death** was presented with KEYTRUDA + lenvatinib vs chemotherapy in the ITT population  
(HR 0.65, 95% CI: 0.55–0.77; **nominal p-value<0.0001**)

Analysis cut-off date: 1 March 2022.

Figure adapted from Makker V et al. Presented at ESMO 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC.

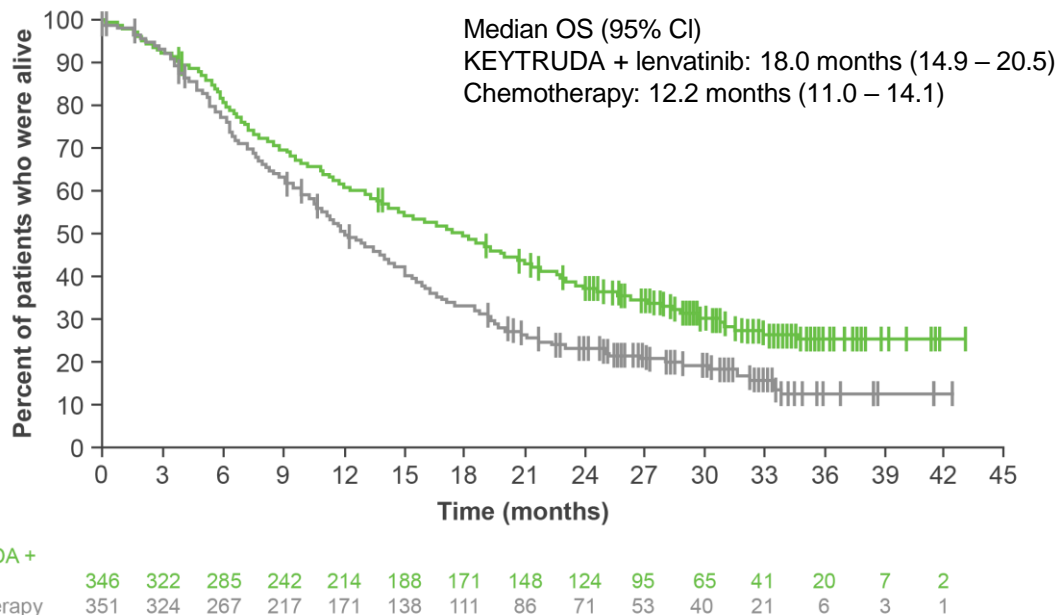
Available at: <https://www.medicines.org.uk/emc/product/2498/smpc>. Accessed June 2025; 3. MSD data on file.

Prescribing Information: **KEYTRUDA UK**; **lenvatinib UK**





# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior OS vs chemotherapy in patients who were pMMR at the final analysis (nominal p-value)<sup>1-3</sup>



**A 30% reduction in the risk of death** was presented with KEYTRUDA + lenvatinib vs chemotherapy in the pMMR population (HR 0.70, 95% CI: 0.58–0.83; **nominal p-value<0.0001**)

Analysis cut-off date: 1 March 2022.

Figure adapted from Makker V et al. Presented at ESMO 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient..

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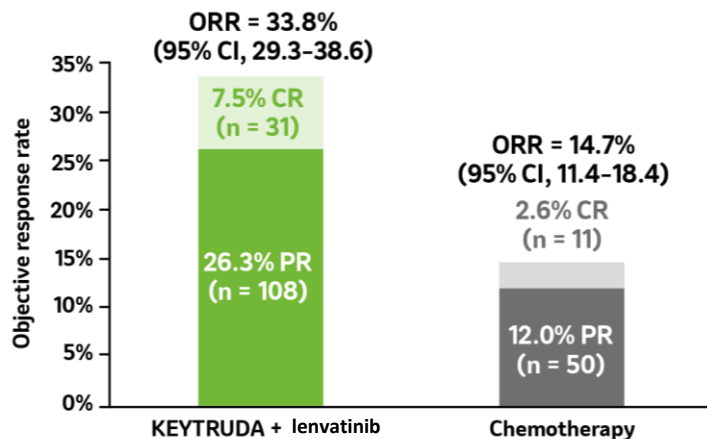
Prescribing Information: **KEYTRUDA UK**; **lenvatinib UK**





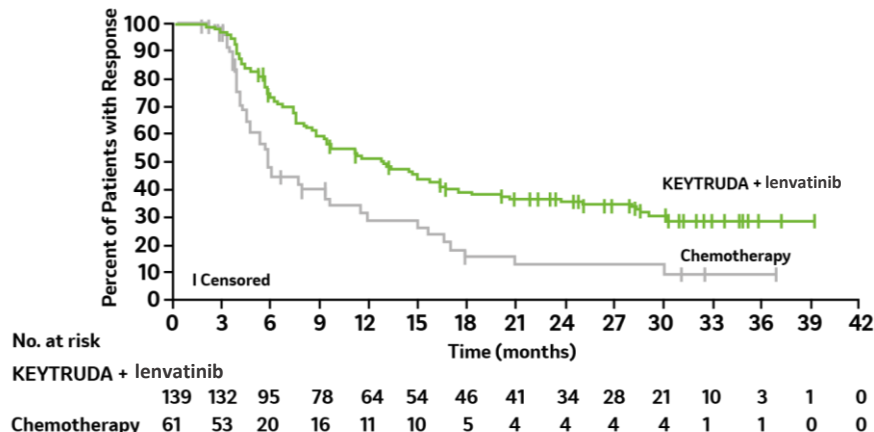
# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior ORR and DOR vs chemotherapy in all patients (final analysis)

## All-comer ORR<sup>a</sup>



33.8% of patients achieved an objective response with KEYTRUDA + lenvatinib vs 14.7% of patients receiving chemotherapy

## All-comer DOR<sup>b</sup>



Median DOR was 12.9 months (95% CI: 1.6–39.5) with KEYTRUDA + lenvatinib vs 5.7 months (95% CI: 0.0–37.1) with chemotherapy

A tabular view of objective responses and duration of response is shown in the appendix. Click [here](#) to view.

Analysis cut-off date: 1 March 2022.

Figures adapted from Makker V et al. *Presented at ESMO 2022*. Tick marks indicate censored data.

<sup>a</sup>95% CI based on binomial exact CI method. Only confirmed CRs and PRs are included in ORR. DCR: KEYTRUDA + lenvatinib 72.3 (67.7–76.5), chemotherapy 46.6 (41.8–51.6). At the interim analysis, 18 (KEYTRUDA + lenvatinib) and 9 (chemotherapy) patients with pMMR tumours had a CR of 27 (KEYTRUDA + lenvatinib) and 11 (chemotherapy) patients in the all-comer population had a CR; <sup>b</sup>Median DOR is derived from product-limit KM method for censored data and includes patients with CR or PR. Median TTR (for patients with CR or PR): KEYTRUDA + lenvatinib 2.1 (1.5–23.3), chemotherapy 2.1 (1.0–7.4).

BOR, best objective response; CI, confidence interval; CR, complete response; DCR, sum of the complete, partial and stable disease rates; DOR, duration of response; ORR, objective response rate; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)

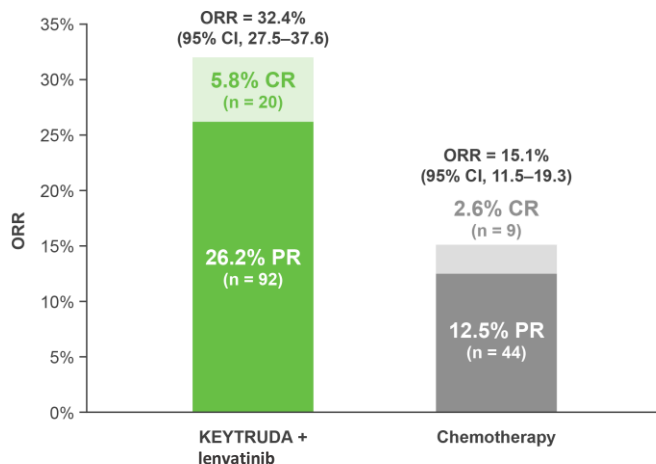






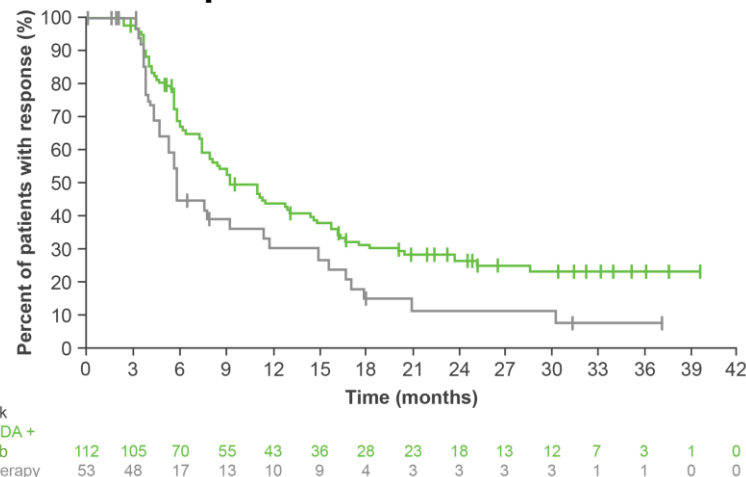
# KEYNOTE-775: KEYTRUDA + lenvatinib presented superior ORR and DOR vs chemotherapy in patients who were pMMR (final analysis)

**pMMR ORR<sup>a</sup>**



**32.4% of patients achieved an objective response with KEYTRUDA + lenvatinib vs 15.1% of patients receiving chemotherapy**

**pMMR DOR<sup>b</sup>**



**Median DOR was 9.3 months (95% CI: 1.6–39.5) with KEYTRUDA + lenvatinib vs 5.7 months (95% CI: 0.0–37.1) with chemotherapy**

A tabular view of objective responses and duration of response is shown in the appendix. Click [here](#) to view.

Analysis cut-off date: 1 March 2022.

Figures adapted from Makker V et al. *Presented at ESMO 2022*. Tick marks indicate censored data.

<sup>a</sup>95% CI based on binomial exact CI method. Only confirmed CRs and PRs are included in ORR. DCR (BOR of CR, PR or SD at 7 weeks or more after randomisation): KEYTRUDA + lenvatinib 72.0 (66.9–76.6), chemotherapy 46.4 (41.1–51.8). DCR: KEYTRUDA + lenvatinib 72.3 (67.7–76.5), chemotherapy 46.6 (41.8–51.6). At the interim analysis, 18 (KEYTRUDA + lenvatinib) and 9 (chemotherapy) patients with pMMR tumours had a CR of 27 (KEYTRUDA + lenvatinib) and 11 (chemotherapy) patients in the all-comer population had a CR; <sup>b</sup>Median DOR is derived from product-limit KM method for censored data and includes patients with CR or PR. Median TTR (for patients with CR or PR): KEYTRUDA + lenvatinib 2.1 (1.5–23.0), chemotherapy 3.5 (1.0–7.4).

CI, confidence interval; CR, complete response; DOR, duration of response; ORR, objective response rate; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9–13, 2022.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: Summary of AEs in all treated patients



AE, n (%)	KEYTRUDA + lenvatinib (n=406)	Chemotherapy (n=388)
Any AE	405 (99.8)	386 (99.5)
Grade $\geq 3$	361 (88.9)	282 (72.7)
Serious AEs	214 (52.7)	118 (30.4)
AE leading to dose reductions <sup>a</sup>	270 (66.5)	50 (12.9)
AE leading to treatment interruption <sup>b</sup>	281 (69.2)	105 (27.1)
KEYTRUDA <sup>c</sup>	203 (50.0)	–
lenvatinib <sup>c</sup>	238 (58.6)	–
KEYTRUDA + lenvatinib	125 (30.8)	–
AE leading to discontinuation	134 (33.0)	31 (8.0)
KEYTRUDA <sup>c</sup>	76 (18.7)	–
lenvatinib <sup>c</sup>	125 (30.8)	–
KEYTRUDA + lenvatinib	57 (14.0)	–
AE leading to death	23 (5.7)	19 (4.9)

For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

Analysis cut-off date: 26 October 2020.

<sup>a</sup>Includes lenvatinib only or chemotherapy; <sup>b</sup>Includes KEYTRUDA or lenvatinib; <sup>c</sup>Regardless of the action taken with the other drug in the combination arm. Table adapted from Makker V et al. *N Engl J Med* 2022 (and supplementary appendix).

AE, adverse event; SmPC, Summary of Product Characteristics.

Makker V et al. *N Engl J Med* 2022;386:437–448 (and supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: AEs with $\geq 25\%$ incidence in either arm



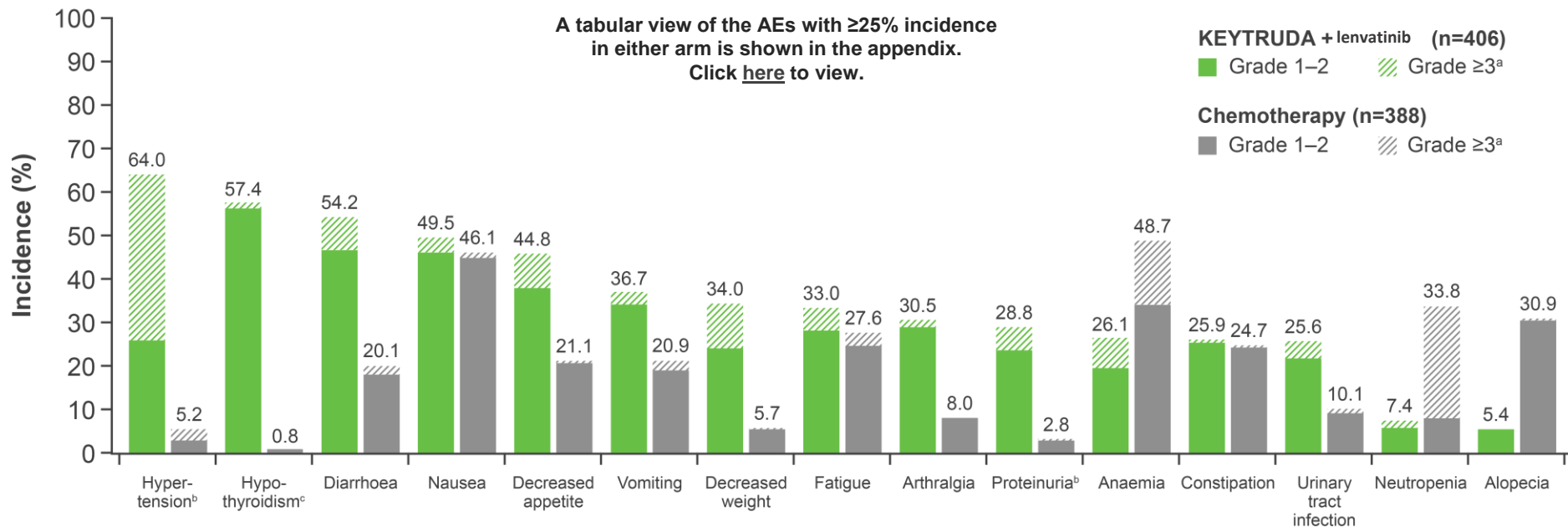
A tabular view of the AEs with  $\geq 25\%$  incidence in either arm is shown in the appendix.  
Click [here](#) to view.

KEYTRUDA + lenvatinib (n=406)

■ Grade 1–2    ▨ Grade  $\geq 3^a$

Chemotherapy (n=388)

■ Grade 1–2    ▨ Grade  $\geq 3^a$



For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

**Analysis cut-off date: 26 October 2020.** <sup>a</sup>Among patients who received KEYTRUDA + lenvatinib, 5.7% died due to Grade 5 AEs (GI disorder in 1.2% of patients, cardiac disorder in 0.5%, general disorder in 1.5%, infection in 0.7%, decreased appetite in 0.2%, and neoplasms, nervous system disorder, psychiatric disorder, renal disorder, reproductive disorder or respiratory disorder in 0.2% each). Among patients who received chemotherapy, 4.9% died due to Grade 5 AEs (cardiac disorder in 1.0%, general disorder in 1.3%, infection in 1.5%, subdural haematoma in 0.3% and respiratory disorder in 0.8%); <sup>b</sup>Clinically significant AE with lenvatinib; <sup>c</sup>AE of interest with KEYTRUDA. Figure adapted from Makker V et al. *N Engl J Med* 2022.

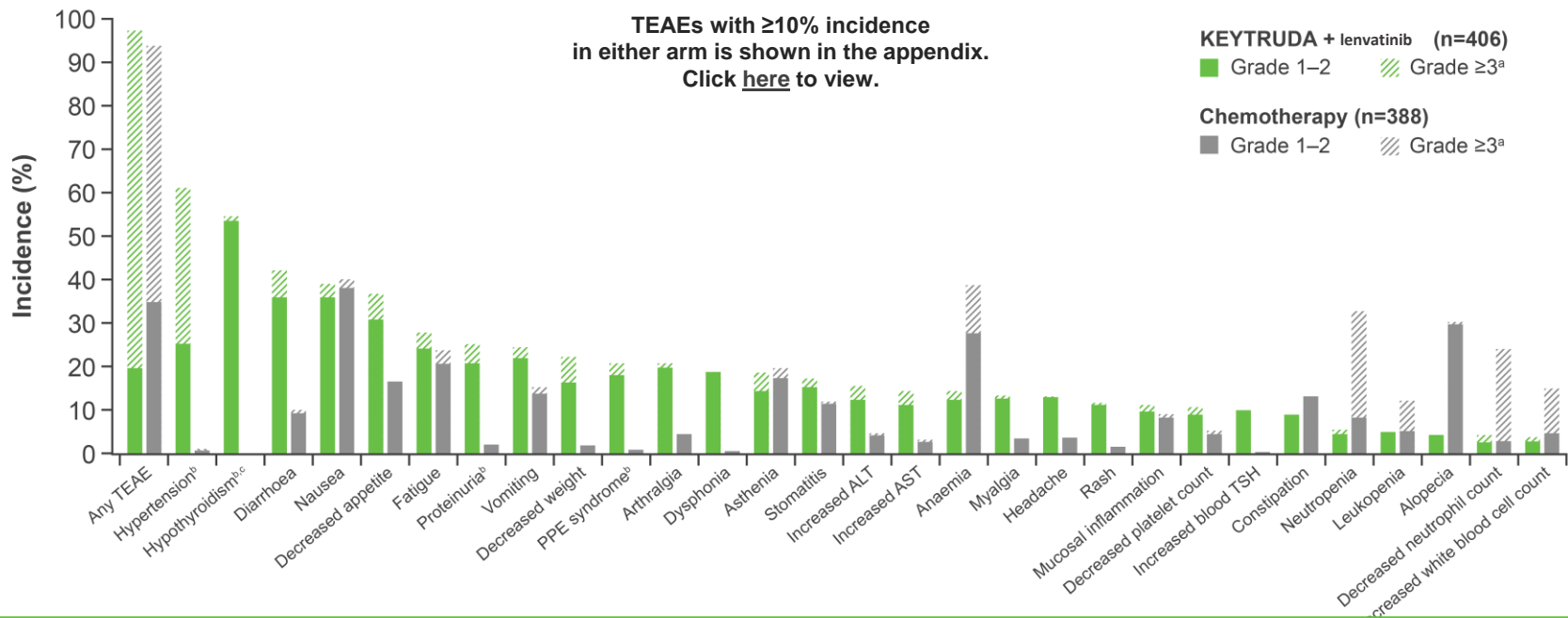
AE, adverse event; GI, gastrointestinal; SmPC, Summary of Product Characteristics. Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: Treatment-emergent adverse events with $\geq 10\%$ incidence in either arm



For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

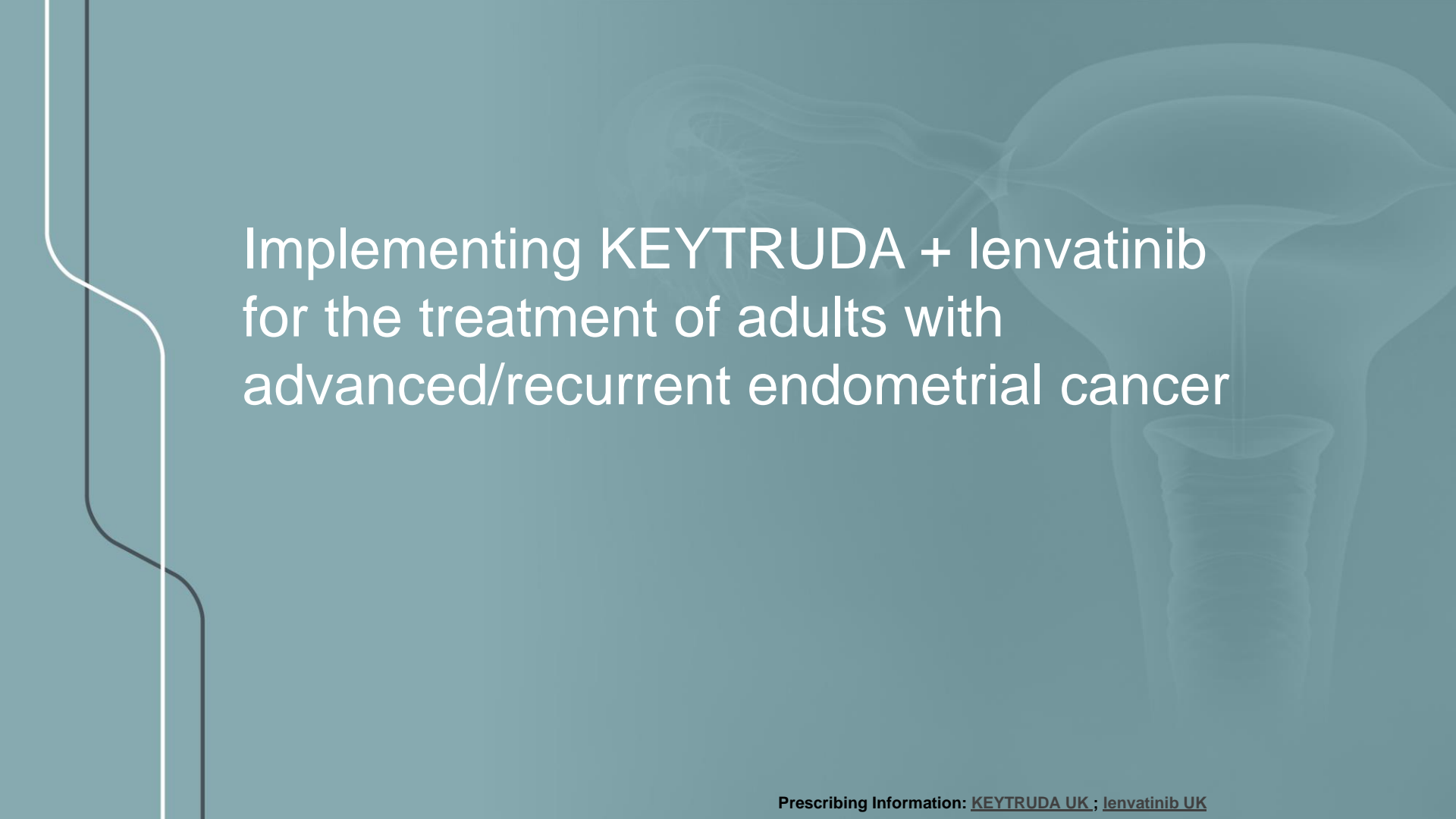
Analysis cut-off date: 26 October 2020.

<sup>a</sup>TEAEs led to death in 1.5% of patients in the KEYTRUDA + lenvatinib group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]); <sup>b</sup>Clinically significant AEs for lenvatinib in all patients; <sup>c</sup>AE of interest for KEYTRUDA in all patients. Figure adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix). AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; PPE, palmar-plantar erythrodysesthesia; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event; TSH, thyroid-stimulating hormone

Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# Implementing KEYTRUDA + lenvatinib for the treatment of adults with advanced/recurrent endometrial cancer



# KEYTRUDA + lenvatinib dosing

## KEYTRUDA<sup>1</sup>



200 mg Q3W  
or  
400 mg Q6W



IV infusion over  
30 minutes

- Continue treatment with KEYTRUDA until disease progression or unacceptable toxicity occurs
- No dose reductions of KEYTRUDA are recommended. KEYTRUDA should be withheld or discontinued to manage AEs as described in the SmPC
- Immune-related AEs, including severe and fatal cases, have occurred in patients receiving KEYTRUDA
  - Please refer to the SmPC for further information on KEYTRUDA dosing: [United Kingdom](#)

## lenvatinib<sup>2</sup>



20 mg QD



Oral administration

- Continue treatment with lenvatinib for as long as there is clinical benefit or until unacceptable toxicity occurs
- For AEs thought to be related to lenvatinib, upon resolution/improvement of an AE to Grade 0–1 or baseline, treatment should be resumed at a reduced dose of lenvatinib
  - Please refer to the SmPC for further information on lenvatinib dosing: [United Kingdom](#)

AE, adverse event; IV, intravenous; Q3W, every 3 weeks; Q6W, every 6 weeks; QD, once daily; SmPC, Summary of Product Characteristics.

1. KEYTRUDA (pembrolizumab) SmPC. Available at: <https://www.medicines.org.uk/emc/product/2498/smcp>. Accessed June 2025;

2. lenvatinib (lenvatinib) SmPC. Available at: <https://www.medicines.org.uk/emc/product/6840/smcp>.

Accessed June 2025.

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)



# KEYNOTE-775: Summary





# KEYNOTE-775: Summary of efficacy and safety in the ITT population



**KEYTRUDA + lenvatinib showed statistically significant (interim analysis), clinically meaningful improvements in PFS and OS vs chemotherapy in all patients with advanced, metastatic or recurrent endometrial cancer**



## **KEYTRUDA + lenvatinib presented a higher PFS vs chemotherapy (final analysis)**

- Median (95% CI) PFS: 7.3 (5.7–7.6) months with KEYTRUDA + lenvatinib vs 3.8 (3.6–4.2) months with chemotherapy (HR 0.56, 95% CI: 0.48–0.66; nominal p-value<0.0001)

## **KEYTRUDA + lenvatinib presented a higher OS vs chemotherapy (final analysis)**

- Median (95% CI) OS: 18.7 (15.6–21.3) months with KEYTRUDA + lenvatinib vs 11.9 (10.7–13.3) months with chemotherapy (HR 0.65, 95% CI: 0.55–0.77; nominal p-value<0.0001)



## **Safety data were generally consistent with the known AE profiles of each agent (final analysis)**

- Grade ≥3 AEs occurred in 88.9% of patients in the KEYTRUDA + lenvatinib arm and 72.7% of patients in the chemotherapy arm
- Of those treated, patients in the KEYTRUDA + lenvatinib arm had a higher proportion of discontinuations of any trial agent (33.0%) compared with patients in the chemotherapy arm (8.0%)
  - The main reason for discontinuation in both treatment arms was disease progression





# KEYNOTE-775: Appendix



Click the links below to navigate to the section of interest

**PFS in key  
subgroups  
(ITT population)**

**PFS in key  
subgroups  
(pMMR population)**

**OS in key  
subgroups  
(ITT population)**

**OS in key  
subgroups  
(pMMR population)**

**Objective responses  
in the ITT and  
pMRR populations**

**Objective responses  
in the dMMR  
population**

**AEs with  $\geq 25\%$   
incidence in  
either arm**

**TEAEs with  $\geq 10\%$   
incidence in  
either arm (1)**

**TEAEs with  $\geq 10\%$   
incidence in  
either arm (2)**

**QoL**

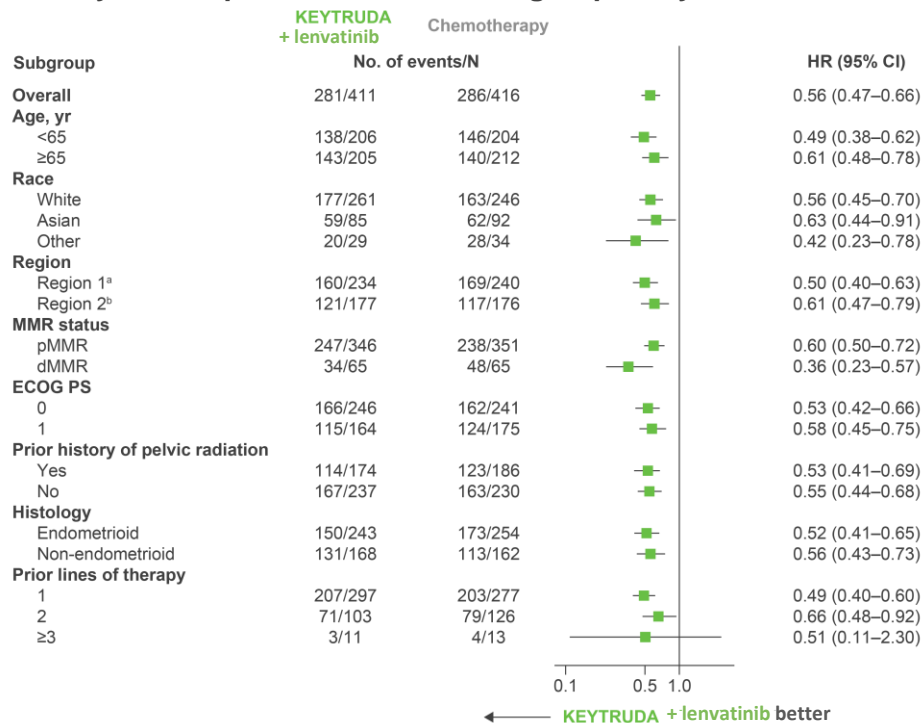




# KEYNOTE-775: PFS in key subgroups (ITT population)



No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn



Analysis cut-off date: 26 October 2020.

<sup>a</sup>Europe, USA, Canada, Australia, New Zealand and Israel; <sup>b</sup>Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; PFS, progression-free survival; MMR, mismatch repair; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

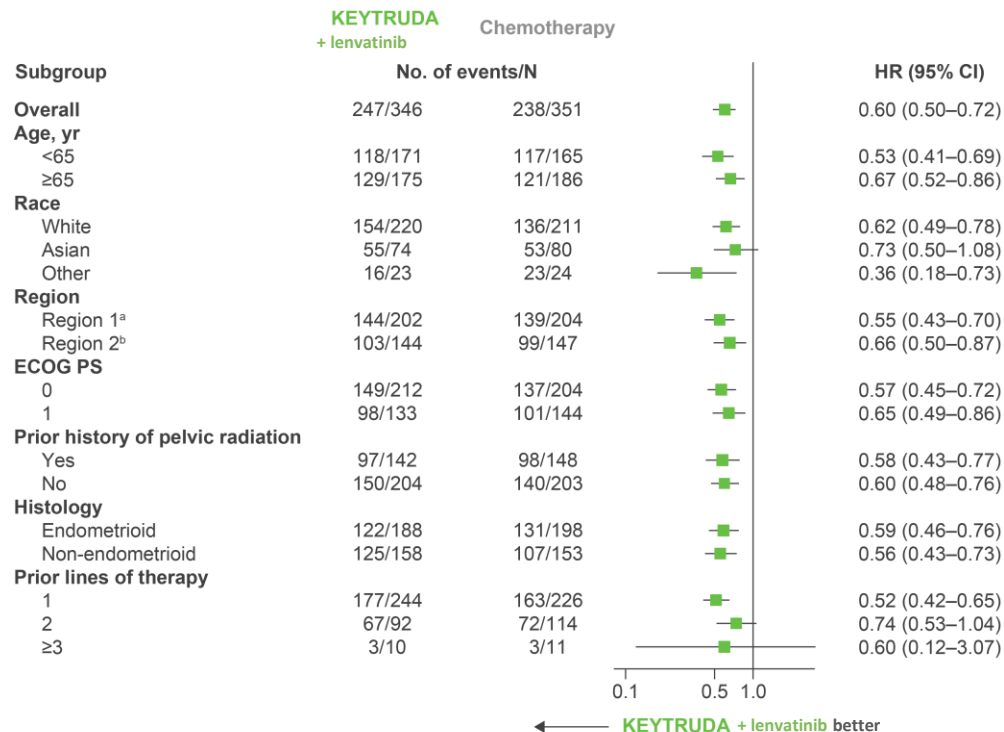
Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)





# KEYNOTE-775: PFS in key subgroups (pMMR population)

No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn



Analysis cut-off date: 26 October 2020.

<sup>a</sup>Europe, USA, Canada, Australia, New Zealand and Israel; <sup>b</sup>Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; PFS, progression-free survival; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)

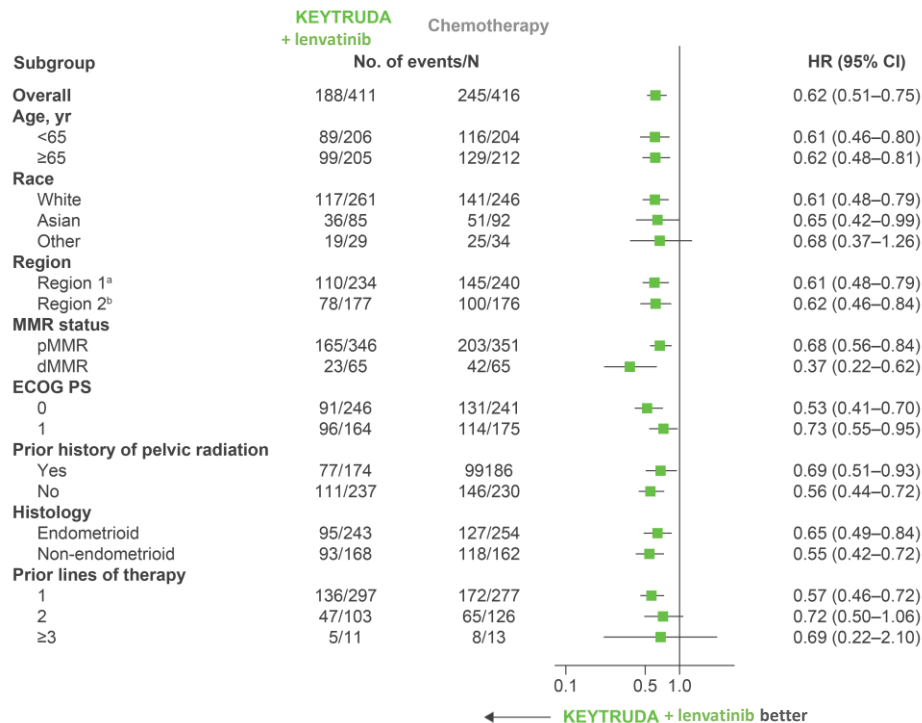




# KEYNOTE-775: OS in key subgroups (ITT population)



No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn



Analysis cut-off date: 26 October 2020.

<sup>a</sup>Europe, USA, Canada, Australia, New Zealand and Israel. <sup>b</sup>Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; MMR, mismatch repair; OS, overall survival; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)

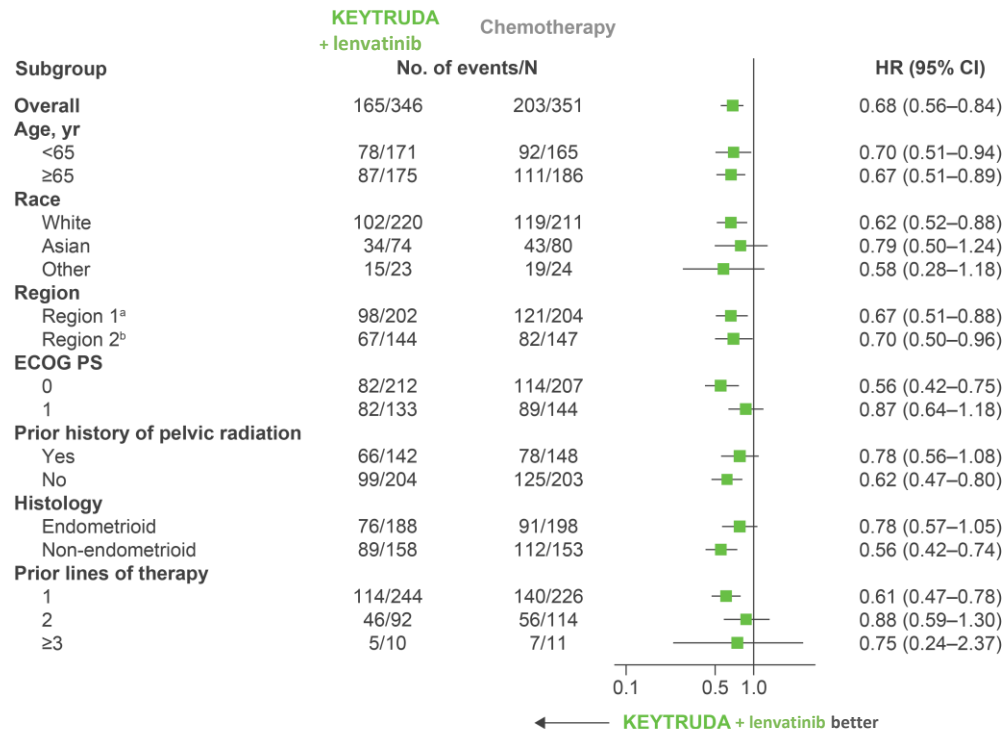




# KEYNOTE-775: OS in key subgroups (pMMR population)



No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn



Analysis cut-off date: 26 October 2020.

<sup>a</sup>Europe, USA, Canada, Australia, New Zealand and Israel. <sup>b</sup>Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; OS, overall survival; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: Objective responses in the pMMR and all-comers populations (final analysis)



	pMMR population		All-comer population	
Endpoint	KEYTRUDA + lenvatinib (n=346)	Chemotherapy (n=351)	KEYTRUDA + lenvatinib (n=411)	Chemotherapy (n=416)
ORR difference %, (95% CI) <sup>a</sup>	17.2 (11.0–23.5)		19.2 (13.4–24.9)	
% (95% CI) <sup>b</sup>	32.4 (27.5–37.6)	15.1 (11.5–19.3)	33.8 (30.3–38.6)	14.7 (11.4–18.4)
BOR, % (95% CI) <sup>a</sup>				
CR <sup>c</sup>	5.8 (3.6–8.8)	2.6 (1.2–4.8)	7.5 (5.2–10.5)	2.6 (1.3–4.7)
PR <sup>c</sup>	26.6 (22.0–31.6)	12.5 (9.3–16.5)	26.3 (22.1–30.8)	12.0 (9.1–15.5)
SD	46.5 (41.2–51.9)	39.6 (34.4–44.9)	45.0 (40.1–50.0)	40.1 (35.4–45.0)
PD	15.6 (11.9–19.9)	30.8 (26.0–35.9)	14.8 (11.5–18.7)	29.6 (25.2–34.2)
NE <sup>d</sup>	0.6 (0.1–2.1)	2.0 (0.8–4.1)	1.2 (0.4–2.8)	1.9 (0.8–3.8)
NA <sup>e</sup>	4.9 (2.9–7.8)	12.5 (9.3–16.5)	5.1 (3.2–7.7)	13.7 (10.5–17.4)
Disease control rate, % (95% CI) <sup>a,f</sup>	72.0 (66.9–76.6)	46.4 (41.1–51.8)	72.3 (67.7–76.5)	46.6 (41.8–51.6)
Median DOR <sup>g,h</sup>	9.3 (1.6–39.5)	5.7 (0.0–37.1)	12.9 (1.6–39.5)	5.7 (0.0–37.1)
Median TTR <sup>h</sup>	2.1 (1.5–23.0)	3.5 (1.0–7.4)	2.1 (1.5–23.0)	2.1 (1.0–7.4)

Analysis cut-off date: 1 March 2022.

a95% CI based on binomial exact CI method; bbased on Miettinen & Nurminen method stratified by MMR status; ECOG PS, geographic region and prior history of pelvic radiation (for all-comer population and pMMR populations; cFor best OR of CR or PR, only confirmed responses are included; dPost-baseline assessment(s) available, but NE; eNo post-baseline assessment available for response evaluation; fDefined as BOR of CR, PR or SD at 7 weeks or more after randomisation; gFrom product-limit (Kaplan—Meier) method for censored data; hIncludes participants with CR or PR.

BOR, best overall response; CI, confidence interval; CR, complete response; DOR, duration of response; ITT, intention-to-treat; mo, months; MMR, mismatch repair; NA, not assessed; NE, not estimable; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: Objective responses in the dMMR population



Endpoint	KEYTRUDA + lenvatinib (n=411)	Chemotherapy (n=416)
ORR		
n	26	8
% (95% CI)	40 (28–53)	12 (5–23)
BOR		
CR		
n	9	2
% (95% CI)	14 (7–25)	3 (<1–11)
PR		
n	17	6
% (95% CI)	26 (16–39)	9 (3–19)
SD		
n	25	28
% (95% CI)	38 (27–51)	43 (31–56)

Endpoint	KEYTRUDA + lenvatinib (n=411)	Chemotherapy (n=416)
BOR (continued)		
PD		
n	7	15
% (95% CI)	11 (4–21)	23 (14–35)
NE		
n	3	1
% (95% CI)	5 (1–13)	2 (0–8)
NA		
n	4	13
% (95% CI)	6 (2–15)	20 (11–32)
Median DOR (range), mo	NR (2.1–20.4)	4.1 (1.9–15.6)
Median TTR (range), mo	2.9 (1.7–16.3)	1.9 (1.8–3.7)
Disease control		
n	48	31
% (95% CI)	74 (61–84)	48 (35–60)

Analysis cut-off date: 1 March 2022.

Table adapted from Makker V et al. *N Engl J Med* 2022.

BOR, best overall response; CI, confidence interval; CR, complete response; dMMR, mismatch repair deficient; DOR, duration of response; mo, months; NA, not assessed; NE, not estimable; NR, not reached; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: AEs with $\geq 25\%$ incidence in either arm



AE, n (%)	KEYTRUDA + lenvatinib (n=406)		Chemotherapy (n=388)	
	Any grade	Grade $\geq 3^a$	Any grade	Grade $\geq 3^a$
Hypertension <sup>b</sup>	260 (64.0)	154 (37.9)	20 (5.2)	9 (2.3)
Hypothyroidism <sup>c</sup>	233 (57.4)	5 (1.2)	3 (0.8)	0
Diarrhoea	220 (54.2)	31 (7.6)	78 (20.1)	8 (2.1)
Nausea	201 (49.5)	14 (3.4)	179 (46.1)	5 (1.3)
Decreased appetite	182 (44.8)	32 (7.9)	82 (21.1)	2 (0.5)
Vomiting	149 (36.7)	11 (2.7)	81 (20.9)	9 (2.3)
Decreased weight	138 (34.0)	42 (10.3)	22 (5.7)	1 (0.3)
Fatigue	134 (33.0)	21 (5.2)	107 (27.6)	12 (3.1)
Arthralgia	124 (30.5)	7 (1.7)	31 (8.0)	0
Proteinuria <sup>b</sup>	117 (28.8)	22 (5.4)	11 (2.8)	1 (0.3)
Anaemia	106 (26.1)	25 (6.2)	189 (48.7)	57 (14.7)
Constipation	105 (25.9)	3 (0.7)	96 (24.7)	2 (0.5)
Urinary tract infection	104 (25.6)	16 (3.9)	39 (10.1)	4 (1.0)
Neutropenia	30 (7.4)	7 (1.7)	131 (33.8)	100 (25.8)
Alopecia	22 (5.4)	0	120 (30.9)	2 (0.5)

For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

<sup>a</sup>Among patients who received KEYTRUDA + lenvatinib, 5.7% died due to Grade 5 AEs (GI disorder in 1.2% of patients, cardiac disorder in 0.5%, general disorder in 1.5%, infection in 0.7%, decreased appetite in 0.2%, and neoplasms, nervous system disorder, psychiatric disorder, renal disorder, reproductive disorder or respiratory disorder in 0.2% each). Among patients who received chemotherapy, 4.9% died due to Grade 5 AEs (cardiac disorder in 1.0%, general disorder in 1.3%, infection in 1.5%, subdural haematoma in 0.3% and respiratory disorder in 0.8%); <sup>b</sup>Clinically significant AE with lenvatinib; <sup>c</sup>AE of interest with KEYTRUDA. Table adapted from Makker V et al. *N Engl J Med* 2022. AE, adverse event; GI, gastrointestinal; SmPC, Summary of Product Characteristics.

Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)







# KEYNOTE-775: Treatment-emergent adverse events with $\geq 10\%$ incidence in either arm (1)



AE, n (%)	KEYTRUDA + lenvatinib (n=406)		Chemotherapy (n=388)	
	Any grade	Grade $\geq 3^a$	Any grade	Grade $\geq 3^a$
Any TEAE	395 (97.3)	316 (77.8)	364 (93.8)	229 (59.0)
Hypertension <sup>b</sup>	248 (61.1)	146 (35.9)	4 (1.0)	1 (0.3)
Hypothyroidism <sup>b,c</sup>	221 (54.4)	4 (1.0)	0	0
Diarrhoea	171 (42.1)	25 (6.2)	42 (10.8)	3 (0.8)
Nausea	158 (38.9)	12 (3.0)	157 (40.5)	4 (1.0)
Decreased appetite	149 (36.7)	24 (5.9)	64 (16.5)	0
Fatigue	113 (27.8)	15 (3.7)	92 (23.7)	12 (3.1)
Proteinuria <sup>b</sup>	102 (25.1)	18 (4.4)	4 (1.0)	0
Vomiting	99 (24.4)	10 (2.5)	59 (15.2)	6 (1.5)
Decreased weight	90 (22.2)	24 (5.9)	7 (1.8)	0
PPE syndrome <sup>b</sup>	84 (20.7)	11 (2.7)	3 (0.8)	0
Arthralgia	84 (20.7)	4 (1.0)	17 (4.4)	0
Dysphonia	76 (18.7)	0	2 (0.5)	0
Asthenia	75 (18.5)	17 (4.2)	76 (19.6)	9 (2.3)
Stomatitis	70 (17.2)	8 (2.0)	46 (11.9)	2 (0.5)

For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

<sup>a</sup>TEAEs led to death in 1.5% of patients in the KEYTRUDA + lenvatinib group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]);

<sup>b</sup>Clinically significant AEs for lenvatinib in all patients; <sup>c</sup>AE of interest for KEYTRUDA in all patients. Table adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

AE, adverse event; PPE, palmar-plantar erythrodysesthesia; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)





# KEYNOTE-775: Treatment-emergent adverse events with $\geq 10\%$ incidence in either arm (2)



AE, n (%)	KEYTRUDA + lenvatinib (n=406)		Chemotherapy (n=388)	
	Any grade	Grade $\geq 3^a$	Any grade	Grade $\geq 3^a$
Increased ALT	63 (15.5)	13 (3.2)	14 (3.6)	2 (0.5)
Increased AST	58 (14.3)	13 (3.2)	12 (3.1)	2 (0.5)
Anaemia	58 (14.3)	8 (2.0)	150 (38.7)	43 (11.1)
Myalgia	54 (13.3)	3 (0.7)	13 (3.4)	0
Headache	53 (13.1)	1 (0.2)	14 (3.6)	0
Rash	47 (11.6)	2 (0.5)	6 (1.5)	0
Mucosal inflammation	45 (11.1)	6 (1.5)	35 (9.0)	3 (0.8)
Decreased platelet count	43 (10.6)	7 (1.7)	20 (5.2)	3 (0.8)
Increased blood TSH	40 (9.9)	0	1 (0.3)	0
Constipation	36 (8.9)	0	51 (13.1)	0
Neutropenia	22 (5.4)	4 (1.0)	127 (32.7)	95 (24.5)
Leukopenia	20 (4.9)	0	47 (12.1)	27 (7.0)
Alopecia	17 (4.2)	0	117 (30.2)	2 (0.5)
Decreased neutrophil count	17 (4.2)	7 (1.7)	93 (24.0)	82 (21.2)
Decreased white blood cell count	15 (3.7)	4 (1.0)	58 (14.9)	40 (10.3)

For further information on the safety of KEYTRUDA + lenvatinib, please refer to the SmPC: [United Kingdom](#)

<sup>a</sup>TEAEs led to death in 1.5% of patients in the KEYTRUDA + lenvatinib group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]).

Table adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event; TSH, thyroid-stimulating hormone.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#); [lenvatinib UK](#)

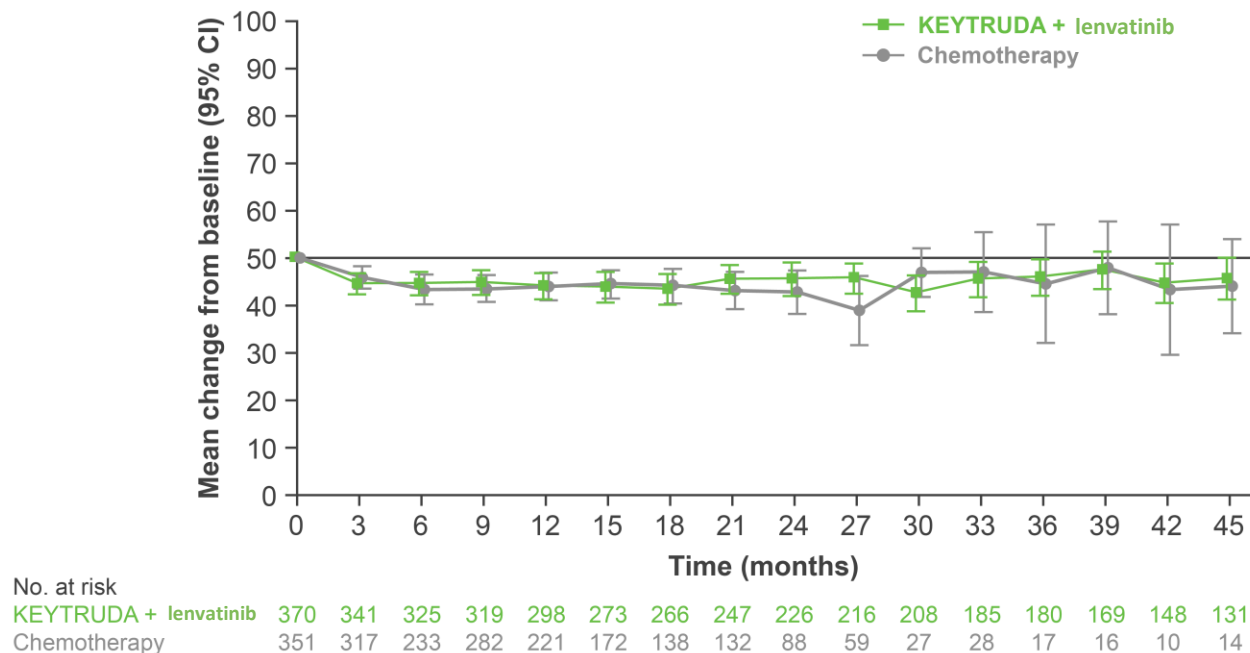




# KEYNOTE-775: No substantial between-group differences were observed in the QLQ-C30 global health status QoL scores over time



## EORTC QLQ-C30 Global Health Status/QoL



Analysis cut-off date: 26 October 2020.

Figure adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

CI, confidence interval; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; QoL, quality of life.

Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: [KEYTRUDA UK](#) ; [lenvatinib UK](#)

